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Transplants and Implants: The Coming of the LVAD

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In the field of permanent cardiac assistance, left ventricular assist techniques have probably witnessed the greatest progress during the last several years. Several different approaches to long-term support are now emerging as realistic possibilities, to join the one established technique for cardiac replacement: transplantation.

The latter procedure has, of course, advanced to the point that it can be considered a mature therapy. Although donor-host matching, immunosuppressive regimens, and graft preservation are still areas for research, allografts can provide acceptable treatment, limited only by their cost and the undersupply of donor organs. The use of heterografts is an obvious area of investigation. Here, too, however, undersupply is a consideration. The concerns of animal rights activists and the requirements of those investigating HIV disorders probably will preclude extensive exploration of this source of donor organs for some time to come. The conclusion that many clinicians, scientists, and planners have drawn is that alternatives to transplantation are an urgent priority.

The total artificial heart, which had excited such strong hopes when its clinical investigation began, will undoubtedly reappear in a new incarnation. It is evident, however, that the magnitude and variety of the problems requiring resolution are substantial. A number of years will elapse before we are ready to reassess the clinical utility of the total artificial heart.

Left ventricular assist devices are riding the crest of a strong wave that is carrying parallel-flow and in-series approaches to the forefront of clinical investigation. Both categories are represented today by multiple systems, being developed by groups around the world. In Europe, these teams are led by Drs. E. Bucherl in Germany, F. Unger and E. Wolner in Austria, J. Vasku in Czechoslovakia, and V. Shumakov in the Soviet Union. In Japan, Drs. K. Atsumi and T. Akutsu are both working with the Aisin Seiki Company. In the United States, the National Heart, Lung, and Blood Institute has nurtured, among others, the teams spearheaded by Drs. W. Pierce at the Pennsylvania State College of Medicine, W. Bernhard and Thermedics, Inc. in Boston, P. Portner of Novacor with colleagues at Stanford University in California, Y. Nosé of the Cleveland Clinic and the Nimbus Company (California), D. Lederman and P. Singh of Abiomed, Inc. in Boston, and our own group at Sinai Hospital and L.VAD Technology, Inc. in Michigan.

PARALLEL-FLOW LEFT VENTRICULAR ASSIST SYSTEMS

These systems' implanted conduits shunt blood from the left atrium or left ventricle to the aorta. The systems under development differ in such features as anatomic placement of system components, including sites for implantation of inflow and outflow conduits, materials for fabrication of the blood interface, method of transferring power across the intact skin, and types of control circuitry utilized, among other characteristics. These systems also share certain characteristics, and these are of crucial relevance to the selection of a particular system for a particular patient. All use the pusher-plate in one or another configuration to impart energy to the blood stream. They do not depend on intact left ventricular function. They can assume 100% of the left ventricular workload. In addition, all share the requirement for a compliance chamber of some type as a temporary reservoir for gas or fluid displaced during the assist pump cycle. Moreover, each of these systems places a relatively

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large surface area of artificial material in contact with the blood. Finally, valves are required (Fig. 1).

Although the permanent versions of these systems are intended to be totally implantable, pneumatically actuated designs for use over periods as long as several weeks have been undergoing clinical evaluation. Patients include those with postcardiotomy low-output syndrome in whom intraaortic balloon pumping (IABP) and pharmacologic support are insufficient and those in end-stage left ventricular failure who require bridging to cardiac transplantation. Experiences with the temporary versions of these systems confirm that considerations of host-device interaction and system reliability are by no means negligible.

If maximal support of the left ventricle and minimal requirement for tethering of the patient to external apparatus are among the attributes that have been optimized in the design of parallel-flow ventricular assist systems, then safety and reliability have been the paramount goals in the development of an in-series solution to the problem of permanent left ventricular assistance.

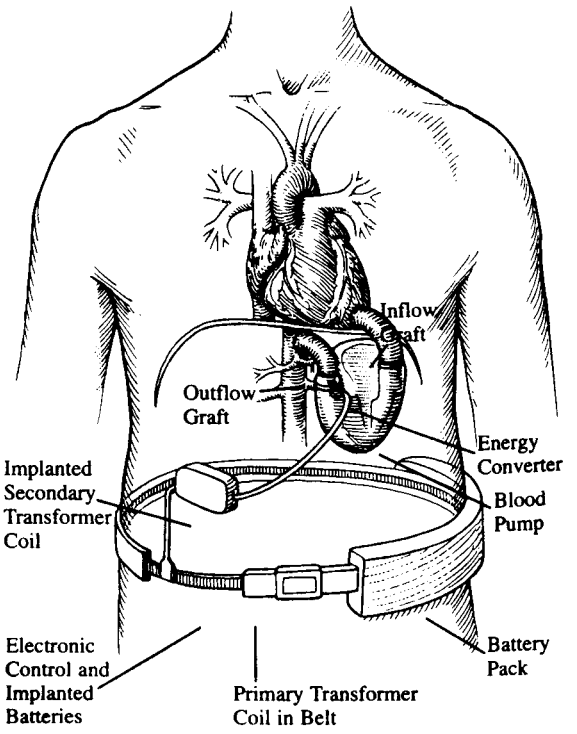

FIG. 1. Schematic of a representative parallel left ventricular assist system. (Source: The Working Group on Mechanical Circulatory Support. Artificial heart and assist devices: directions, needs, costs, societal and ethical issues. Bethesda, Maryland: National Heart, Lung, and Blood Institute, May 1985; p. 10).

PERMANENT IN-SERIES ASSISTANCE

To achieve these benefits, the permanent auxiliary ventricle being developed by our group improves upon the established virtues of IABP, the one technique of assisted circulation to cross over the threshold to routine clinical use during the 20 years since our first clinical introduction of this system in 1967.

The positive features of IABP are several. In many thousands of patients with different types of decompensation, it has demonstrated efficacy in stabilizing the circulation. The hemodynamic aberrations in which IABP is effective include cardiogenic shock that arises in the course of acute myocardial infarction, low flow states before and after cardiopulmonary bypass for cardiac surgery, and advanced left ventricular failure. As compared with parallel-flow left ventricular assist techniques, IABP introduces a small surface area of artificial material into the bloodstream. This probably accounts for the low incidence of adverse effects on the hemostatic mechanisms reported in the world literature. Still another advantage is that the technique has been studied exhaustively. Its physiologic actions, ancillary management, and potential problems are well understood by cardiologists and surgeons throughout the world.

The permanent mechanical auxiliary ventricle, now being prepared for clinical readiness testing, incorporates a pumping bladder in the wall of the descending thoracic aorta (Fig. 2). In that location, it replicates IABP's hemodynamic actions.

The permanent auxiliary ventricle enjoys advantages which balloon pumping cannot provide. Because the permanent auxiliary ventricle is incorporated in the wall of the aorta, the required blood-contacting surface area of biomaterial is far smaller than that demanded by any other cardiac assist system for permanent application. Blood-contacting valves are not used. It is capable of doubling the pumping capacity of the IABP. In addition, when deflated, the permanent auxiliary ventricle minimally alters the anatomy and geometry of the aorta. Accordingly, in stand-by mode it functions as a small, passive aortic graft. This is true of no other long-term cardiac assist system implemented so far. Parallel-flow systems, in particular, must be operated essentially continuously to avert thromboembolic complications.

Together, the permanent auxiliary ventricle's small surface area of biomaterial, avalvular design, and preservation of the topography of the aorta create two important benefits. First, anticoagulation is not required. Second, cardiac assistance with the

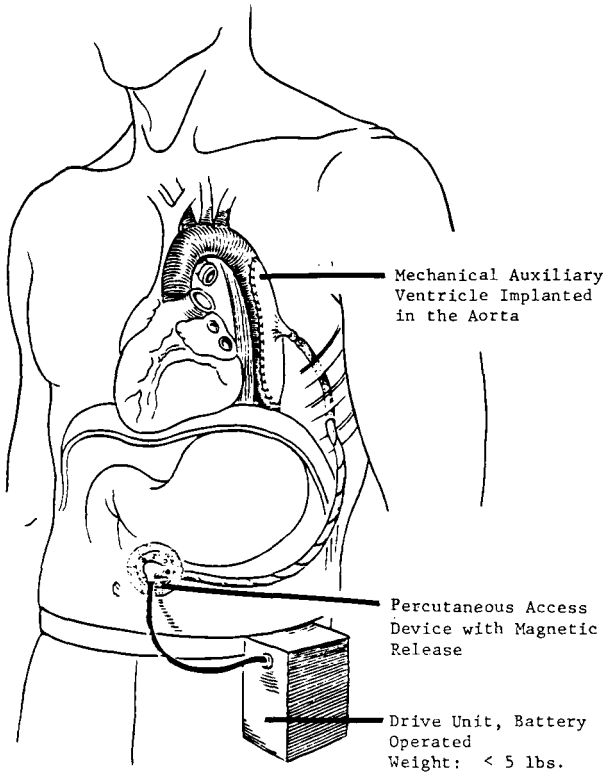

FIG. 2. Schematic of an in-series permanent auxiliary ventricle in situ. Gas conduit leads through percutaneous access device to gas supply and control circuitry.

permanent auxiliary ventricle can be discontinued at will for any length of time without putting the patient at heightened risk of thromboembolic complications. One of the important consequences is that failure of the actuating components of the auxiliary ventricle does not demand heroic emergency efforts to protect the patient from thromboembolic catastrophe.

The permanent auxiliary ventricle offers other advantages. Since it is pneumatically actuated, most hardware is extracorporeal. So placed, it does not raise the question of compromised function of thoracic or abdominal structures. Furthermore, its components are for the most part readily repaired or replaced. It is true that this arrangement presupposes reliable, permanent transcutaneous passage. Formerly a daunting difficulty, the design of a reliable percutaneous access device appears to have been advanced to the stage where an innovative approach using an autologous cell cultured device-tissue interface makes clinical use feasible. Finally, the auxiliary ventricle system has a certain simplicity of engineering design. There is no necessity for matching the dynamic outputs of multiple components which are relatively difficult to "tune" to the patient's requirements in vivo.

Of course, there are also disadvantages. Since the auxiliary ventricle, like the intraaortic balloon pump, is an in-series system, it presupposes some degree of intact cardiac mechanical and electrophysiologic function. The auxiliary ventricle will give little, if any, support to a patient in ventricular fibrillation. By the same token, the auxiliary ventricle cannot assume the total left ventricular workload. And the fact that the actuating and control apparatus are extracorporeal means that some degree of tethering is mandatory. But in the current state of the art, these components, including batteries, can be packaged in a belt-worn unit weighing about 5 lb, which the patient can wear without significant inconvenience.

CONSIDERATIONS IN SELECTING AN LV ASSIST SYSTEM

In the near future, clinicians will be called upon to assess the risks and benefits of various mechanical approaches to assisting the patient with intractable left ventricular failure. The outlines of a scheme are emerging for classifying the various elements of such computations. These elements, tentatively, may be said to consist of at least six items.

Urgency of the Indication for Mechanical Ventricular Assistance

For patients who need a ventricular assist device to enable recovery from post-cardiotomy low-flow syndrome, other things being equal, a parallel-flow system able to contend with ventricular arrhythmias and replace ventricular function completely for as long as necessary is the treatment of choice. On the other hand, when assist-device implantation need not be accomplished as an emergency procedure, considerations of the magnitude and duration of support the patient is likely to need become pertinent. The patient's response to a trial of IABP in the catheterization laboratory is predictive of the response to the permanent auxiliary ventricle.

Type of Cardiac Assistance Required

The clinician can choose biventricular, right ventricular, predominantly or exclusively left ventricular.

Medical Conditions Influencing Choice of Assist Technique

Irreversible pulmonary hypertension, as an example, may render heart-lung transplantation the only feasible therapy. Other conditions might impair the patient's ability to withstand the incorpo-

ration of a substantial surface area of biomaterial into the bloodstream. A patient with a history of disseminated intravascular coagulation, or aberrant hematologic and hemostatic response to vascular implants, or certain occlusive vascular diseases, e.g., widespread cerebral arteriolosclerosis, would be, other things being equal, a candidate for a system requiring a smaller rather than a larger surface area of biomaterial. Moderate to severe aortic valve disease would require treatment in order for a permanent auxiliary ventricle implantation to be helpful.

Magnitude of Assistance Required

This refers not only to the increment in cardiac output required to yield relief of symptoms, but also the likelihood that complete replacement of left ventricular function will be needed in the course of severe ventricular arrhythmias. As noted, IABP provides a clear-cut test of the efficacy of hemodynamic support by the permanent auxiliary ventricle in alleviating chronic congestive failure.

Probable Duration and Type of Ventricular Support

The natural history of left ventricular failure treated by means of a permanently implanted assist device has for obvious reasons received little study. There are, nevertheless, some suggestive, though not well controlled, observations indicating that considerable amelioration of myocardial functional deficits is one of the responses to prolonged mechanical ventricular support. Other things being equal, a non-obligatory system may have advantages for certain patients.

Patient's Psychosocial Capabilities

Some assist regimens may prove to require greater compliance on the patient's part than others. Patients with parallel-flow systems are likely to require, for example, frequent monitoring of the hemostatic mechanisms and of therapeutic efforts to influence them. Noncompliant personalities may be unsuited to some forms of mechanical ventricular assistance but not others.

It goes without saying that the relative weights to be given to these elements, as well as the trade-offs among them and other potentially relevant elements, are matters demanding analysis and empirical investigation.

A FAMILY OF APPROACHES TO THE FAILING LEFT VENTRICLE

As the tentativeness and nonspecificity of the above listing indicates, considerable research will be necessary to determine criteria for matching patients to left ventricular assist techniques. Still, it seems probable that such research will confirm a general impression: that the techniques currently under investigation do not compete with one another. No single one seems to meet all the criteria that may be relevant to a given patient's care. Clinical patient management can only benefit from the pursuit of a coalition of specific system configurations for specific problems. We are just at the beginning of the period in which we will identify the considerations germane to the tailoring of mechanical assist treatment, and are then in the fortunate position of having an emerging family of approaches to the failing left ventricle.